

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW
BIRMINGHAM HIP RESURFACING
(BHR) HIP IMPLANT PRODUCTS
LIABILITY LITIGATION

MDL-17-md-2775
Hon. Catherine C. Blake

This Document Relates to
ALL ACTIONS

**[PROPOSED] STIPULATED
ORDER RE: DISCOVERY OF
ELECTRONICALLY STORED
INFORMATION**

1. PURPOSE

This [Proposed] Stipulated Order (“Order”) will govern the discovery and use of electronically stored information (“ESI”) in this case as a supplement to the Federal Rules of Civil Procedure, this Court’s Protective Order of June 16, 2017, and any other applicable orders and rules. The parties each reserve the right to seek exceptions, amendments, or modifications to this Order from the Court for good cause shown.

2. COOPERATION

The parties are aware of the importance the Court places on cooperation and commit to cooperate in good faith throughout the matter.

3. E-DISCOVERY LIAISONS

Within thirty (30) days from the date of this Order, each party will identify an E-discovery Liaison who will be primarily responsible for meeting and conferring concerning ESI. Each E-discovery Liaison will:

- a. be knowledgeable about the party’s e-discovery efforts;
- b. be, or have reasonable access to those who are, familiar with the party’s electronic systems and capabilities in order to explain those systems and answer relevant questions; and

c. be, or have reasonable access to those who are, knowledgeable about the technical aspects of e-discovery, including electronic document storage, organization, and format issues, and relevant information retrieval technology, including search methodology.

Each party will notify the other of any changes of its designated E-discovery Liaison.

4. EXCHANGE OF ESI-RELATED INFORMATION

Smith & Nephew, Inc. (“Smith & Nephew”) has provided or will provide the information listed in items (a) and (b) below. The parties agree and understand that Smith & Nephew’s investigation related to this litigation is ongoing, and that the information provided reflects the knowledge and understanding as of the date provided. Smith & Nephew agrees to amend or supplement this information in a timely manner if it learns that in some material respect it is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known during the discovery process or in writing:

a. A list of custodians comprised of current and former Smith & Nephew employees (from any department) most likely to have discoverable information potentially relevant to Plaintiffs’ claims, including pertinent job title(s) and/or brief description of pertinent responsibilities.

b. A statement of information regarding Smith & Nephew’s information technology systems, including relevant document retention policies and any known deficiencies.

5. MEET AND CONFER & DEFICIENCY PROCESS

The parties have begun, and will continue, to meet and confer to discuss and attempt to reach an agreement on the appropriate scope and limitations of production of ESI. The parties will discuss possible options for ensuring an efficient discovery process, such as the possible use of search terms or technology assisted review, the possible use of testing and sampling, relevant date ranges, possible custodians that may have potentially discoverable information, any

obstacles to accessing and producing ESI, information demonstrative of adequate quality controls, and the timing of productions.

If a party has good cause to believe that a producing party's discovery efforts have been deficient, the parties will meet and confer with the goal of identifying a means by which the producing party can provide assurances of the reasonableness of its discovery efforts. As used in this section, "good cause" requires more than mere speculation; the party must offer some concrete evidence of a deficiency in the producing party's discovery process. If the parties are unable to agree upon a means by which the producing party can provide assurances of the reasonableness of its discovery efforts, the parties will submit the dispute to the Court in the form of a joint discovery submission.

If a party contends that the production of materials sought are outside the scope of Fed. R. Civ. P. 26(b)(1), the parties agree to meet and confer, if necessary, to attempt to resolve the issue. Nothing in this Order shall prevent a party from seeking Court intervention with respect to such issue if the parties are unable to resolve it themselves or from preventing any other party from opposing any relief sought.

6. ESI SEARCH

The parties will discuss and attempt to reach an agreement on search methodologies with the goal of limiting the scope of review for production, minimizing the need for motion practice, and facilitating production in accordance with the deadlines set by the Court or agreed upon by the parties. Agreement on a search methodology does not relieve a party of its obligations under the Federal Rules.

a. Search Terms:

1. Prior to using search terms to cull the universe of collected documents into a review database, the producing party will provide a list of proposed search terms to the requesting party and the parties will meet and confer regarding any additional terms proposed by the requesting party. Once the list of terms is agreed upon, the producing party will provide a search term hit list or hit report after global de-duplication. The list or report should include the number of documents that hit on each term, the number of unique documents that hit on each term (documents that hit on a particular term and no other term on the list), and the total number of documents that would be returned by using the proposed search term list (including families). The parties will use the report to modify terms, if necessary.

2. If a party disputes a specific term as being overly broad, the parties will meet and confer to determine the best method for assessing whether the term is properly tailored, and the best method for modifying the term, if appropriate.

3. If the parties are unable to resolve through the meet and confer process disputes regarding search terms to cull the universe of collected documents into a review database, the parties will submit the dispute to the Court in the form of a joint discovery letter with a discussion of the relevance and proportionality associated with the search terms in dispute.

4. After the parties have agreed on search terms, the producing party agrees to perform a quality check of the data that does not hit on any terms (the Null Set) by selecting a statistically random sample

of documents from the Null Set. The size of the statistically random sample shall be calculated using a confidence level of 95% and a margin of error of 2%. If a significant number of documents potentially relevant to Plaintiffs' claims are found during the Null Set review, the parties will meet and confer regarding the addition or modification of search terms and/or other measures appropriate to ensure to a reasonable extent that potentially relevant documents are promoted to the review database.

- b. Identification of Responsive Documents: To the extent necessary, the parties will meet and confer regarding the methods to be used to review and identify documents responsive to a requesting party's particular requests for production. Those methods may include technology-assisted review, request-specific search terms and strings, linear review, or any other method agreed upon by the parties.
- c. Technology Assisted Review ("TAR"): Prior to using predictive coding/technology assisted review, the producing party will notify the opposing party with ample time to meet and confer in good faith regarding a mutually agreeable protocol for the use of such technologies or alternatives. This discussion will include:
 - 1. Whether any culling measures were taken prior to the application of TAR and a quality control protocol for that part of the process;
 - 2. The vendor being used to manage the application of the technology;
 - 3. The method(s) used to derive the seed or exemplar set;
 - 4. The method for validating the computer decisions; and
 - 5. The measures taken to check the quality of the computer decisions.

The party employing TAR agrees to a goal of 85% stabilization rate for its process, meaning that of one hundred random documents sampled from the

reviewable set, 85% would be accurately coded by the computer. If the 85% stabilization rate is not reasonable achievable, the parties agree to meet and confer to adjust this number.

7. FORM OF PRODUCTION

a. The parties agree that attending to issues relating to form of production at the outset of discovery facilitates the efficient and cost effective conduct of discovery. Appendix A sets forth technical specifications that the parties propose to govern the form of production of ESI in this litigation, absent other agreement by the parties. Among other things, the proposed technical specifications incorporate the directive of Fed. R. Civ. P. 34(b)(2)(E)(iii) and provide that a party need not produce ESI in more than one form, unless otherwise agreed to in limited circumstances (as contemplated in the technical specifications). The parties agree to produce documents in PDF, TIFF, native and/or paper or a combination thereof as set forth in Appendix A. For good cause, a requesting party may request the production of documents in a format other than as specified in this Order. The parties shall thereafter meet and confer, and the producing party shall not unreasonably deny such requests. The parties agree not to degrade the searchability of documents as part of the document production process. The parties also recognize that in some instances where documents have been produced in a form other than native, subsequent production of the same documents in native form may be warranted for certain purposes.

b. A party may de-duplicate globally or on a custodian level. Upon request, each party will disclose the methodology it used to de-duplicate. The parties agree that an e-mail that includes content in the “bcc” or other blind copy field shall not be treated as a duplicate of an e-mail that does not include content in the “bcc” or other blind copy field. Alternatively, the producing party may produce the e-mail containing the bcc by itself.

c. The parties share a desire to ensure that ESI is produced in an acceptable, searchable format. The parties recognize that certain, limited ESI may not be amenable to the proposed technical specifications. The parties will meet and confer in good faith to reach

agreement regarding these issues and the appropriate form of production, and will seek Court intervention if necessary.

8. TIMING OF PRODUCTIONS

After requests for production of documents have been propounded, the parties will meet and confer regarding the method of identifying and schedule for rolling production of documents responsive to those requests. The parties agree and understand that the identification and review of potentially responsive documents is time-consuming, yet the producing party shall endeavor in good faith to begin such production within a reasonable time, and shall further endeavor to make any subsequent productions in the rolling production on a regular basis thereafter. The producing party will communicate with the requesting party regarding any significant delays that it anticipates or experiences during the review and production process.

9. AUTHENTICITY

This Order establishes a rebuttable presumption that documents produced by the parties are authentic, if said documents were either created or authored by the producing party's employees, officers, or directors. No further evidence to establish authenticity for these documents need be provided.

10. CONFIDENTIALITY, PRIVACY, AND SECURITY OF INFORMATION

a. The Protective Order entered on June 16, 2017, will govern the treatment of confidential information produced in this litigation.

b. The producing party may redact information that is subject to attorney-client privilege or work-product protection (as explained below), or contains Personally Identifiable Information ("PII") or protected health information, or is otherwise prohibited from disclosure, including:

- i. The names, addresses, Social Security numbers, tax identification numbers, and any other personal identifying information of patients,

health care providers or other voluntary reporters reporting specific adverse events, and individual patients participating in clinical studies or referenced in adverse event reports.

- ii. Social Security numbers, passwords, telephone conference line numbers, tax identification numbers and other private personal information of employees or other persons in any records.

c. A redaction shall state “Privileged,” or “Protected Data,” to set forth the general basis of the redaction. The producing party shall also provide a field in the load file that reflects whether a document is redacted and, if so, the general type(s) of redaction(s) on the document. To the extent practical, the producing party will endeavor to leave as visible headings or similar non-substantive information concerning the redacted information to facilitate identification of the general nature of the redacted information. The producing party need not produce a redaction log, as the reason for each redaction will be stated on the face of the document and in the metadata. Nothing in this paragraph shall prevent a requesting party from seeking additional information if the reason for the redaction is not apparent on the face of the document.

d. Defendant reserves its right to seek to redact information relating to products that are manufactured or marketed by Smith & Nephew other than the Birmingham Hip Resurfacing (BHR) System, (which is comprised of both the Birmingham Hip Resurfacing Femoral Head and the Birmingham Hip Resurfacing Acetabular Cup), where such information is not relevant to any party’s claim or defense in this litigation. Plaintiffs reserve their right to object to these redactions. The parties agree to meet and confer prior to any redactions under this subsection (d).

e. If any disputes arise regarding redactions or issues related thereto, the parties shall meet and confer and allow the producing party a reasonable amount of time to consider the issues and make changes before engaging in any motion practice with respect to redacted material.

11. PRIVILEGED INFORMATION AND ATTORNEY WORK-PRODUCT

- a. The parties agree that they do not intend to disclose information subject to a claim of attorney-client privilege or attorney work-product protection.
- b. The production of privileged or work-product protected documents, ESI, or other information, whether inadvertent or otherwise, is not a waiver of the privilege or protection from discovery in this case or in any other state or federal proceeding. This Order shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502 and shall be enforceable and granted full faith and credit in all other state and federal proceedings by 28 U.S. Code § 1738. In the event of any subsequent conflict of law, the law that is most protective of privilege and work product shall apply. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents or information (including metadata) for relevance, responsiveness, and/or segregation of privileged and/or protected information before production.
- c. Any party receiving what appears to be privileged or work-product protected information shall immediately safeguard the information, shall inform the producing party of the inadvertent production as promptly as reasonably possible, and shall not read, copy, distribute, or otherwise use the information in any manner. Upon confirmation from the producing party that the information was inadvertently produced, the receiving party shall immediately return or destroy the inadvertently produced information, regardless of whether the receiving party agrees with the claim of privilege or protection. Further, the receiving party shall instruct all persons to whom the receiving party has disseminated the privileged or protected information that it is subject to this Order and must be returned or destroyed immediately. Any document or information clawed back under the provisions of this section should be included on the producing party's privilege log at the time that log is produced, or, if the privilege log has already been

produced, on a separate log within 15 days of the clawback.

d. Privilege Logs

- i. To the extent that any documents are withheld from production by either party on the basis of attorney-client privilege, work-product protection, or any other applicable privilege, immunity, or protective doctrine, the producing party will provide, within 30 days of the corresponding production, a privilege log stating the following information for each document:
 - A. the document's Bates number or privilege log entry number;
 - B. the date of the document, which may be extracted in an automated fashion via available metadata;
 - C. the author(s) of the document, which may be extracted in an automated fashion via available metadata;
 - D. the sender(s), addressee(s) and/or recipient(s) of the document in the top most email in an email chain, which may be extracted in an automated fashion via available metadata;
 - E. the title or subject of the document, which may be extracted in an automated fashion via available metadata; and
 - F. the specific privilege, protection, or immunity claimed.
- ii. To the extent the title or subject of a document contains privileged or protected information, the party producing the privilege log will provide in the place of such title or subject a description of the document sufficient to satisfy the purpose of the privilege log without revealing privileged or protected information.
- iii. The parties agree that the following documents are exempt from inclusion on a privilege log:

- A. privileged communication to or from counsel for a party (or counsel's representative) regarding the prosecution or defense of any metal-on-metal claim and/or litigation against Smith & Nephew, and
 - B. work product created by counsel for a party (or counsel's representative) and related to the prosecution or defense of any metal-on-metal claim and/or litigation against Smith & Nephew.
- e. Privilege Challenges
 - i. Nothing in this Order shall constitute a waiver of any party's right to object to a claim of privilege or work-product protection. If a party contends that any document or portion of a document has been erroneously or improperly withheld as privileged or protected, the document or portion thereof shall be treated as properly withheld under the terms of this Order until the parties reach a written agreement or the Court issues an order addressing the appropriate treatment of the subject material.
 - ii. In the event that counsel for a party objects to a claim of privilege or protection, said counsel shall advise counsel for the producing party, in writing, of such objection(s) and the specific documents, identified by Bates number or privilege log entry number, to which each objection pertains (the "Privilege Dispute Notice"). The parties agree that the challenging party will only challenge a reasonable number of documents within any calendar month.
 - iii. After receiving a Privilege Dispute Notice and within a reasonable time for the number of documents challenged, counsel for the producing party shall respond in writing as to whether the producing party will maintain or withdraw its claims of privilege and/or protection for the documents called

into question by the Privilege Dispute Notice. In the response, and for each objection, the producing party must indicate the basis for the privilege and/or protection.

- iv. If the producing party maintains its claim(s) of privilege and/or protection or does not respond within a reasonable time or if the challenging party challenges more than a reasonable number of documents, the parties shall meet and confer in good faith, by phone or in person, to discuss the issue and attempt to resolve the dispute. The parties will make good faith efforts to meet and confer within 5 business days of a request for a meet and confer.
- v. If, after meeting and conferring in good faith, the parties are unable to resolve the dispute, the party may file a motion with the Court seeking to challenge the privilege and/or protection of the documents or portions of documents at issue and/or the number of documents challenged.
- vi. Pending a resolution of the motion, the materials at issue shall be treated as privileged and/or protected, in keeping with the producing party's claims.

IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

Dated: December 14, 2017

By:

/s/ Robert K. Jenner

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**PURSUANT TO STIPULATION AND FOR GOOD CAUSE SHOWN, IT IS SO
ORDERED.**

DATED:

Judge Catherine C. Blake

Appendix A

Technical Specifications for Production

PRODUCTION OF DOCUMENTS ORIGINATING AS PAPER

For documents that have originated in paper format, the following specifications should be used for their production.

- Images should be produced as single page TIFF group IV format imaged at 300dpi. In the event that a requesting party believes that color-for-color replication is necessary for full comprehension of a produced document, the requesting party will request a color copy of the document from the producing party, and the producing party will make all reasonable efforts to provide a color copy. Original document orientation should be maintained (i.e., portrait to portrait and landscape to landscape). Bates numbers, confidentiality designations, and redactions should be burned into the TIFF image files. TIFF images files should be provided in a self-identified “Images” folder.
- Each filename must be unique and match the Bates number of the page. The filename should not contain any blank spaces and should be zero padded (for example ABC00000001).
- Media may be delivered on CDs, DVDs, or External USB hard drives, or via SFTP. Each media volume should have its own unique name and a consistent naming convention (for example ZZZ001 or SMITH001).
- A unitization file, in standard format (e.g., Opticon, Summation DII) showing the Bates number of each page, the appropriate unitization of the documents and the entire family range, will accompany each TIFF document.
- Documents should be provided with Concordance-compatible image and data load files (i.e., .OPT and .DAT files) using standard Concordance delimiters. The first line in each Concordance compatible .DAT file should be the header containing the agreed-upon field names, and each subsequent line should contain the fielded data for each document. Concordance-compatible image and data load files (i.e., .OPT and .DAT files) should be provided in a self-identified “Data” folder. At a minimum, the following fields should be included with paper productions:
 - PRODBEG
 - PRODEND
 - Custodian
 - Number of Pages
 - Text Path
- To the extent that documents have been run through an Optical Character Recognition (OCR) Software in the course of reviewing the documents for production, full text should also be delivered for each document. Text should be delivered on a document level in an appropriately formatted text file (.txt) that is named to match the first bates number of the

document with a relative path to the text file in the delimited load file. Each text file should be provided in a self-identified "Text" folder.

PRODUCTION OF EMAIL AND NON-DATABASE ELECTRONIC DOCUMENTS

A party may produce e-mail messages individually or as part of an e-mail chain, provided that any e-mail chain that is forwarded with a previous e-mail in the chain deleted or modified will be produced separately.

To the extent they include relevant information, attachments, enclosures, and/or exhibits to any responsive parent documents should be produced and proximately linked to the respective parent documents. Attachments, enclosures, or exhibits that relate solely to products not at issue in this litigation and not relevant to a claim or defense are subject to the meet and confer provision in section 10(d).

For standard documents, emails, and presentations originating in electronic form, documents should be produced as TIFF images using the same specifications above with the following exceptions:

- Provide a delimited text file (using the delimiters detailed above) containing the following extracted metadata fields where they exist in the file being produced:

Beginning Production Number or PRODBEG
Ending Production Number or PRODEND
Beginning Attachment Range or PRODBEGATT
Ending Attachment Range or PRODENDATT
Custodian
Confidentiality Designation
Redacted
Redaction Type
Document Type
File Name
Doc Ext
File Size
MD5 Hash Value
Date Last Modified
Date Created
Date Last Accessed
Date Sent
Date Received
Author or FROM
Recipients or TO
Copyees or CC
Blind Copyees or BCC
Email Subject
Path to Native File

Conversation Index

Text Path

Original Folder Path (For edocs, the path to the document on the network or hard drive; for email, the path to the email in the email system.)

- In lieu of creating an “Other Custodian” field, the parties agree that any individual listed as a custodian per Section 4.a. of this Order shall be considered a custodian of any email for which he or she is included in the TO, FROM, CC, or BCC fields.
- Extracted full text should also be delivered for each electronic document. However, if a document has been redacted, OCR of the redacted document will suffice in lieu of extracted text. Also, if extracted text is not available in the native file, the documents should be processed by an OCR tool prior to production to extract available text so that the record is searchable. The extracted full text should be delivered on a document level according to the specifications above similar to paper documents.
- Foreign language text files and metadata should be delivered with the correct encoding to enable the preservation of the document’s original language.
- All spreadsheets should be produced in their native format and in the order that they were stored in the ordinary course of business, i.e. emails that attach spreadsheets should not be separated from each other and should be linked using the Attachment Range fields above. Each Native File should be produced with a single-page TIFF placeholder image, which will contain language indicating that the document is being produced as a Native File. Native Files should be provided in a self-identified “Natives” directory. The file name should match the Bates number assigned to the file. The extractable metadata and text should be produced in the same manner as other documents that originated in electronic form. The parties agree to work out a future protocol governing the use and format of documents produced pursuant to this paragraph at trial, depositions or hearings (such as converting to TIFF images in accordance with the above protocol). For documents that contain redacted text, the parties may either apply the redactions directly on the Native File itself or produce TIFF image files with burned in redactions in lieu of a Native File and TIFF placeholder image.
- Notwithstanding the language of Fed. R. Civ. P. 34, upon review the requesting party may ask for certain other documents and/or databases that were initially produced in their petrified (TIFF or PDF) format to be produced in their native format in the event that the petrified version is not reasonably usable. If this is the case, the requesting party will submit a list of bates numbers identifying the documents. The documents should be produced in their unaltered native format with an accompanying text delimited text file (using the delimiters above) that contains the following fields:

Beginning Production Number or PRODBED

Ending Production Number or PRODEND

Beginning Attachment Range or PRODBEGATT

Ending Attachment Range or PRODENDATT

Path to Native File
MD5/SHA1 Hash Value

PRODUCTION OF DATABASES AND OTHER STRUCTURED DATA

Generally, databases should be produced in a mutually agreeable data exchange format, to the extent such data is relevant, available, and proportionate to the needs of the case. To determine the data that is relevant to the document requests, a list of databases and systems used to manage relevant data should be provided with the following information. To the extent a database contains responsive and non-responsive information, only potentially responsive information needs to be disclosed:

Database Name
Description of Database
Software
Primary Business Purpose of Database/System
Operating System
Business Units or Groups Supported
Location of Data
Frequency of Back-up
Related Software/Platforms

If data from a database or other structured data source is responsive to a particular request for production, relevant to a claim in the litigation, and proportionate to the needs of the case, the parties agree to meet and confer regarding the data to be produced from each source, if any, and the form(s) of the production thereof, considering the pertinent fields available, a list of which the producing party will provide to the requesting party as part of the meet and confer process.